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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,851	03/21/2002	Philippe Msika	REGIM-012	2236

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/088,851	MSIKA ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-63,70-72,76,77,82,84,85,88 and 89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-63,70-72,76,77,82,84,85,88 and 89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the election of species: unsaponifiable materials from sunflower oil; atopic dermatitis and topical administration in the reply filed on July 10, 2007 is acknowledged. Upon further consideration, the election/restriction has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 61, 63, 71-72, 76,77, 82, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moy (A) in view of Milkova et al. (U) and Alonso et al (V). Newly applied as necessitated by amendment.

Applicant claims a method of treating a skin condition having a quantity of skin lipids comprising administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil; wherein said quantity of skin lipids increases after administration of the composition; and wherein the skin condition is sensitive skin, dry skin, pruritus, ichtyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation or skin subjected to ultraviolet (UV)

radiation. Applicant further claims the method of claim 61 wherein the subject has an epidermal skin barrier and the skin lipids are lipids of the epidermal skin barrier; wherein the plant oil product is present in an amount of between about 0.01% and 100% by weight relative to the total weight of the composition; wherein the unsaponifiable materials are present in the plant oil product in an amount of 10 to 20% by weight; wherein the composition is administered topically, orally, enterally or parenterally; wherein the composition is applied to the skin, the neighboring mucous membranes and/or the integuments; and, wherein the composition is administered to treat skin that is sensitive, irritated or reactive. Applicant further claims the method of claim 84, wherein the composition is a cosmetic, pharmaceutical or dermatological composition; wherein the cosmetic, pharmaceutical or dermatological composition comprises an oil solution, a water-in-oil emulsion, an oil-in-water emulsion, a micro-emulsion, an oily gel, an anhydrous gel or a dispersion of vesicles, microcapsules or microparticles.

Moy teaches a method of treating skin keratoses or striae distensae, and eliminating or reducing size of skin lesions comprising applying topically, to an affected area of skin, a dermatological acceptable emulsion of oil and water comprising between 1 and 5 weight percent of unsaponifiable avocado seed lipids. See abstract and patent claims 7, 9 and 10. In Column 3, lines 53-60, in addition to apparent alkanes, long chain alcohols, triterpenic alcohols, and sterols, Moy further teaches that the unsaponifiable sterol fraction of avocado oil is known to contain stigmasterol, sitosterol and campesterol. In Column 3, line 62 to Column 4, line 9, Moy suggests that the

topical administration of the reference composition increases skin lipids when applied to affected skin.

The teachings of Moy are set forth above. Moy teaches the instantly claimed invention except for administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil. However, it would have been obvious to one of ordinary skill in the art to add either of the instantly claimed ingredients to the method composition taught by Moy or to replace the method composition taught by Moy with either of the instantly claimed ingredients to provide the instantly claimed method of treating a skin condition because at the time the invention was made Milkova taught that the major sterols of sterol fractions of crude sunflower oil, as well as those of the technical lecithin, the pitch and the deodorizer distillate of the latter oil, are sitosterol, campesterol and stigmasterol. Moreover, Alonso taught that unsaponifiable materials from sunflower oil comprises sitosterol, campesterol and stigmasterol. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add either of the instantly claimed ingredients to the method composition taught by Moy or to replace the method composition taught by Moy with either of the instantly claimed ingredients to provide the instantly claimed method of treating a skin condition because like Alonso, Milkova taught that distillate of sunflower oil and unsaponifiable materials from sunflower oil comprise the same or essentially the same sterol fractions contained in the unsaponifiable sterol fraction of avocado oil having the beneficial functional effect

of increasing lipids in skin when topically administered to skin in need of treatment of rough, dry skin condition, skin lesions such as keratoses, actinic keratoses, scaly skin, stretch marks, aging of the skin caused by sun damage, redness of the skin, mottled skin and dark skin patches. Given the references before him or her, the instantly claimed method of treatment would have been no more than a matter of routine optimization to provide a result effect variable for either the addition or replacement of one functional equivalent for the other wherein it would be highly reasonable to assume that compositions comprising the same or essentially the same ingredients would provide the same beneficial functional effect for treating skin conditions, such as those recited in the Markush of Claim 61 and Claim 82.

As the teachings of Moy indicate that the various proportions and amounts of the ingredients used in the claim-designated composition(s) for the claimed method of treating skin condition are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 61, 63, 71-72, 76,77, 82, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seipel et al. (N or W; Translation of foreign language patent

provided herein.) in view of Ghosh et al. (X), Milkova et al. (U) and Alonso et al (V). Newly applied as necessitated by amendment.

Applicant's claimed invention was set forth above.

Seipel teaches a composition comprising sterol esters, such as stigmasterols and various sitosterols, derived from plant sterols for restoring natural oils in the skin. Seipel further teaches that the acid component of the esters can be derived from fatty acids of a claimed designated compound (I). See page 2. Preferred plant based-fatty acids with 12-18 carbon atoms, such as sunflower fatty acids are used in the making of the composition, wherein the sterol esters can be used in quantities of 1-10 weight percent (see page 2, lines 1-15). The compositions taught by Seipel are combined with conventional excipients known in the art to be acceptable in the making of cosmetic, pharmaceutical or dermatological compositions which can be topically applied to affected areas of skin.

The teachings of Seipel are set forth above. While Seipel beneficially teaches that the reference sterol esters are useful in increasing skin lipids and restoring natural oils to affected skin, Seipel does not expressly teach a method of topically administering the sterol ester-containing compositions to the skin of a subject to provide a method of treating the claim-designated skin conditions wherein the composition comprises at least one plant product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials form sunflower oil. However, it would have been obvious to one of ordinary skill in the art to employ the compositions taught by Seipel and to use either of the instantly claimed ingredients to formulate the composition taught by Seipel

to provide the instantly claimed invention because at the time the invention was made it was known in the art that oil distillate of sunflower and unsaponifiable materials from sunflower oil comprised the same ingredients taught by Seipel as being useful in the making of the reference skin care compositions, as evidenced by the teachings of Ghosh, Milkova and Alonso. For instance, Ghosh taught that sunflower oil distillate was composed of 24.9% unsaponifiable matter with 4.8% tocopherol, 9.7% sterols, 28.8% free fatty acids and 46.3 neutral glycerides. Ghosh further taught hydrolyzed distillate of sunflower oil comprise fatty acid esters, such as oleic acid. Per, the teachings of Milkova and Alonso phytosterols such as the stigmasterols taught to be useful in the formulation of the composition taught by Seipel were known to be contained in the unsaponifiable materials of both oil distillate of sunflower oil and sunflower oil. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable of success to administer the composition taught by Seipel to provide a method of treating a skin condition comprising topically administering the composition to affected skin of a subject to treat skin that is sensitive, irritated or reactive because Seipel teaches that compositions comprising phytosterol esters based on plant fatty acids can be used to emulsify skin, restore natural skin lipids to skin and impart a pleasant feel to skin when applied to rough, dull skin; and, Ghosh, Milkova and Alonso taught that the ingredients taught by Seipel as being useful in the formulation of the disclosed skin care products are readily available from oil distillate of sunflower oil or unsaponifiable materials of sunflower oil.

As the teachings of Seipel indicate that the various proportions and amounts of the ingredients used in the claim-designated composition(s) for the claimed method of treating skin condition are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 61, 63, 71-72, 76, 82, 88 and 89 rejected under 35 U.S.C. 103(a) as being unpatentable over Moy (A) and Werman et al. (U1) in view of Milkova et al. (U) and Alonso et al. (V). Newly applied as necessitated by amendment.

Applicant's claimed invention of 61, 63, 71-72, 76, 82 and 84 was set forth above. Applicant claims a method of treating a skin condition of a subject having a quantity of skin lipids comprising administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil; wherein the quantity of skin lipids increases after administration of the composition; wherein the plant oil product is a food additive for humans and/or animals; and wherein the skin condition is sensitive skin, dry skin, pruritus, ichtyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation or skin subjected to UV radiation.

In Column 3, line 62 bridging Column 4, line 9, Moy discloses a study (A. M. Roberts et al. *G. M. de France*, 82:1975) that showed that the ingestion of unsaponifiable fractions of vegetable oils, such as avocado oil and soybean oil comprising alkanes, long chain alcohols, triterpenic alcohols and sterols, *i.e.,* stigmasterol, sitosterol and campesterol, increased the amount of lipid in the skin and also altered the amount of collagen. In another instance, like Moy, Werman teaches that the oral administration of unsaponifiable materials from avocado oil increased lipogenesis and collagen production in rats.

Each of the teachings of Moy and Werman are set forth above. Moy does not report that the prior art teaches a method of increasing skin lipids in skin comprising the oral administration of the instantly claimed invention. Neither does Werman. However, it would have been *prima facie* obvious to one of ordinary skill in the art to orally administer a composition comprising at least one plant oil selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil because at the time the invention was made Milkova taught that the major sterols of sterol fractions of crude sunflower oil, as well as those of the technical lecithin, the pitch and the deodorizer distillate of the latter oil, are sitosterol, campesterol and stigmasterol. Moreover, Alonso taught that unsaponifiable materials from sunflower oil comprises sitosterol, campesterol and stigmasterol. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add either of the instantly claimed ingredients to the method composition taught by the prior art teachings of Roberts et al. per the

teachings of Moy and/or Werman or to replace the method composition taught by the prior art teachings of Roberts et al. per the teachings of Moy and/or Werman with either of the instantly claimed ingredients to provide the instantly claimed method of treating a skin condition because like Alonso, Milkova taught that distillate of sunflower oil and unsaponifiable materials from sunflower oil comprise the same or essentially the same sterol fractions contained in the unsaponifiable sterol fraction of avocado oil having the beneficial functional effect of increasing lipids in skin when orally administered to skin in need of increasing skin lipids, especially given that it is well known in the art that dysfunction of the skin lipid barrier is prone to the development of skin conditions, such as those recited in the Markush group of each of Claims 61, 82 and 88. Given the references before him or her, the instantly claimed method of treatment would have been no more than a matter of routine optimization to provide a result effect variable for either the addition or replacement of one functional equivalent for the other wherein it would be highly reasonable to assume that compositions comprising the same or essentially the same ingredients would provide the same beneficial functional effect for treating skin conditions, such as those recited in the Markush of Claim 61 and Claim 82. Please note that the claim-designated ingredients of oil distillate or sunflower oil and unsaponifiable materials from sunflower oil are read herein as a food composition for humans and/or animals.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 30, 2008
/Michele Flood/
Primary Examiner, Art Unit 1655